UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,772	10/05/2001	Gary L. Olson	PPI-106CP	4878

959 7590 12/06/2004

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,772	OLSON ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43,45-48 and 50-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43,45-48 and 50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20041006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: In the amendment to the priority claim contained in the response filed July 9, 2004, the serial number and filing date of the parent application need to be re-inserted into the priority claim. Standard format for a priority claim in a U.S. application includes the serial number, the filing date, and an updated status. Appropriate correction is required.

2. Claims 28, 37, 38, and 48 are objected to because of the following informalities: In claims 28 and 37, the semicolon which occurs after "(SEQ ID NO:16)" should be deleted. At claim 38, page 11 of the amendment filed July 9, 2004, line 6, and claim 48, page 14, line 22, the beginning parenthesis before "3-" does not match the end bracket after "enyl". Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the limitation inserted into claim 15 that D can be cyclic alkyl without limitation on the size of the alkyl. The original disclosure limits such cyclic alkyl groups to cyclic C_1-C_6-alkyl groups (compare, e.g., originally-filed claim 20). Applicants have not indicated where the original disclosure supports the new claim limitation.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-43, 45-48, and 50-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 10/001,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '945 application with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. With respect to instant claims 53-56 and 60, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '945 application in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '945 application patent with other known active agents used to treat the same diseases, including those specified in instant claim 58, because it is routine in the pharmaceutical arts to administer multiple drugs intended to treat the same

underlying disease, and because it is prima facie obvious to combine two components, each of which is used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-38 and 50-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-58, 60, 62, 71, and 74-84 of copending Application No. 10/138,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '935 application with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. A difference in intended use does not impart patentability to composition claims where the claimed composition is otherwise anticipated by or obvious. With respect to instant claims 53-56, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '935 application in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '935 application patent with other known active agents used to treat the same diseases, including those specified in instant claim 58, because it is routine in the pharmaceutical arts to administer

multiple drugs intended to treat the same underlying disease, and because it is prima facie obvious to combine two components, each of which is used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-43, 45-48, and 50-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/429,174. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to combine the claimed active agents of the '174 application with pharmaceutically acceptable carriers because it is routine in the pharmaceutical arts to combine therapeutically active agents with pharmaceutically acceptable carriers for ease of storage, transport, measurement, and administration. With respect to instant claims 53-56 and 60, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '174 application in the form of controlled release compositions and in the form of microcapsules because these are conventional forms for pharmaceutically active agents and would not have been expected to interfere with the activity of the claimed active agents. With respect to instant claims 57 and 58, it would have been obvious to one of ordinary skill in the art to administer the claimed active agents of the '174 application patent with other known active agents used to treat the same diseases, including those specified in instant claim 58, because it is routine in the pharmaceutical arts to administer multiple drugs intended to treat the same underlying disease, and because it is prima facie obvious to combine two components, each of

which was used individually for the same purpose. See In re Kerkhoven, 204 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

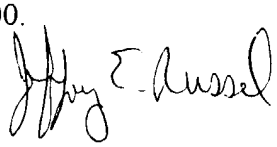
8. The terminal disclaimer filed July 9, 2004 has been approved.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

November 29, 2004